



**US Environmental Protection Agency
Office of Pesticide Programs**

**Extension of the Exclusive Use
Data Protection Period
for Spinosad**

September 19, 2003

VIA OVERNIGHT MAIL

September 19, 2003

George T. LaRocca (7505C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202



**Re: Extension of Exclusive Use Data Protection Period for Spinosad
Spinosad (Chemical No. 110003).**

Dear Mr. LaRocca:

Dow AgroSciences LLC ("DAS") hereby requests EPA to extend the exclusive use of data period for Spinosad (Chemical No. 110003) by an additional three years for a total exclusive use of data period from February 14, 1997 to February 14, 2010. As set forth below, DAS respectfully submits that it has satisfied the requirements for extending the traditional ten year exclusive use of data period for new active ingredients by three years, in accordance with the minor use provisions of FIFRA § 3(c)(1)(F)(ii): specifically, DAS has registered Spinosad, a new reduced-risk active ingredient, on more than nine minor use crops within seven years of its original registration. As well, DAS has satisfied all four conditions of FIFRA § 3(c)(1)(F)(ii): there were insufficient efficacious alternatives registered for use on minor crops to control insect pests controlled by Spinosad; the alternatives posed greater risks; and Spinosad will significantly contribute to managing pest resistance and to Integrated Pest Management ("IPM") programs.

Following the Agency's review of this submission, DAS requests that the Agency confirm in writing that DAS has satisfied the requirements of § 3(c)(1)(F)(ii) and that EPA's Data Submitters List will reflect up to and including February 14, 2010, that DAS has submitted exclusive use data for Spinosad. DAS would be pleased to provide any additional information required by the Agency. As well, DAS representatives would be pleased to meet with the Agency to discuss this request.

Background

EPA first registered the pesticide Tracer® (EPA Reg. No. 62719-267) which contains the new active ingredient Spinosad (a mixture of spinosyn A and spinosyn D) on February 14, 1997. (**Appendix 1**, Notice of Registration). Other registered formulations of Spinosad are Success®, SpinTor®, and Conserve®. **Appendix 2** contains a listing of all data submitted by DAS in support of the original February 14, 1997, registration and **Appendix 3** lists all data DAS has submitted to EPA in support of new (post-February 14, 1997) uses of Spinosad. **Appendixes 2 and 3** identify the study title, MRID and date of submission.

Spinosad is a tetracyclic macrolide fermentation product of the actinomycete, *Saccharopolyspora spinosa* and consists of two structurally related compounds, namely spinosyn A and spinosyn D, which provide the insect control activity. The two spinosyns only differ from each other in the substitution of a hydrogen by a methyl group and have structures consisting of a basic amine group, two sugars, and a larger complex hydrophobic ring. In general, Spinosad controls pests in the insect orders Lepidoptera, Diptera, and Thysanoptera, as well as some species Coleoptera and Orthoptera that consume large amounts of foliage. All EPA registrations of DAS Spinosad pesticides have been as a reduced risk/organophosphate alternative pesticide. (**Appendix 4, *Reduced Risk/Organophosphate Alternative Decisions for Conventional Pesticides***).

DAS Spinosad Minor Use Registrations

To date, DAS has registered Spinosad products for use, to date, on at least 15 minor use crops.¹ **Appendix 5** is a listing of Spinosad minor use crops and crop groupings and their dates of registration. EPA has granted all Spinosad minor use registrations within seven years of February 14, 1997.

DAS satisfies the requirements of subsections I, II, III and IV of FIFRA § 3(c)(1)(F)(ii)

There are insufficient efficacious alternatives registered pesticides available for the minor uses:

As noted, in general, Spinosad provides effective control of pests in the insect orders Lepidoptera, Diptera, and Thysanoptera, as well as some species Coleoptera and Orthoptera that consume large amounts of foliage. It is beyond the scope of this submission to address these insect pests for each minor use Spinosad registration. However, in each case, with increasing restrictions on the registration and reregistration of organophosphate pesticides, many traditional insecticides have been lost for these minor use crops. Moreover, the reduction in traditional insecticides has increased the likelihood of development of pest resistance from the use of fewer alternative pesticides. Therefore, DAS respectfully submits that in each case there are insufficient efficacious alternatives available for the minor uses.

¹ DAS is unaware of an EPA listing of minor use crops. In its *Report on Minor Uses of Pesticides*, EPA identified non-minor crops that are grown on more than 300,000 acres, and thus do not meet the acreage definition of a minor crop. (Report at page 7). The Report stated that the following crops do not meet the acreage qualification for classification as minor crops: almonds, apples, barley, beans (snap and dry), canola, corn (field, sweet and pop), cotton, grapes, hay (alfalfa and other), oats, oranges, peanuts, pecans, potatoes, rice, rye, sorghum, soybeans, sugar beets, sugarcane, sunflower, tobacco, tomatoes, turf and wheat.

The alternatives to Spinosad pose greater risks to the environment or human health:

As noted, EPA has registered Spinosad as a reduced risk pesticide/organophosphate alternative. When applied at recommended rates, Spinosad poses less risk than most insecticides to mammals, birds, fish and beneficial insects.

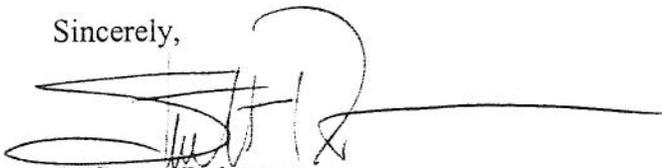
Spinosad plays a significant part in managing resistance and IPM:

Spinosad controls target pests through contact, ingestion and ovicidal activity in a wide variety of crops. When the material contacts an egg, Spinosad will either control the egg immediately or control the larvae through ingestion as they hatch. Its mode of action makes Spinosad effective against resistant pests – and that makes it a valuable partner in resistance management programs. Spinosad is also ideal for IPM programs, allowing growers to harness the natural power of predacious beneficial insects which help suppress secondary pest populations.

Conclusion

For the reasons set forth above, DAS requests the Agency to confirm that DAS has qualified to claim exclusive data use of data rights for Spinosad until February 14, 2010. Should you have any questions or wish to discuss this matter, please do not hesitate to contact me. Thank you for your assistance.

Sincerely,



A. Sterett Robertson
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Attachments:

- Appendix 1** - Notice of Registration
- Appendix 2** - List of Data Submitted in Support of First Spinosad Registration
- Appendix 3** - List of Data Submitted in Support of New Uses
- Appendix 4** - *Reduced Risk/Organoposphate Alternative Decisions* Document
- Appendix 5** - Spinosad Minor Use Crops and Crop Groupings

cc: Debra F. Edwards, EPA – Registration Division
Michele Knorr, EPA – Office of General Counsel
John D. Conner, Jr., McKenna, Long & Aldridge
Rob Gordon, DAS Regulatory Success – America
Robert Fowler, DAS Data Compensation Leader